APR 1 3 2001

K010379

Section 3
IL Test™ Free Protein S - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
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Carol Marble, Regulatory Affairs Manager
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Summary Prepared:

February 7, 2001

Name of the Device:

IL Test™ Free Protein S

Classification Name(s):

864.7290	Factor Deficiency Test	Class II
81GGP	Test, Qualitative and Quantitative Factor Deficient	

Identification of predicate device(s):

K954017	Asserachrom® Free Protein S

Description of the device/intended use(s):

IL Test™ Free Protein S is an *in vitro* diagnostic automated latex ligand immunoassay for the quantitative determination of free protein S in human citrated plasma on IL Coagulation Systems. IL Test™ Free Protein S determines the presence of free protein S by measuring the increase of turbidity produced by the agglutination of the two latex reagents. The degree of agglutination will be directly proportional to the free protein S concentration in the test sample.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

IL Test™ Free Protein S is substantially equivalent to the commercially available predicate device (Asserachrom® Free Protein S) in performance and intended use.

Section 3
IL Test™ Free Protein S - 510(k) Summary (Cont.)
(Summary of Safety and Effectiveness)

Summary of Performance Data:

In method comparison studies evaluating citrated plasma samples with free protein S levels ranging from 12.1 to 139.1% on an ACL Futura (n=143) and an ACL 9000 (n=118), the slopes and correlation coefficients (r) for IL Test™ Free Protein S versus the predicate device are shown below:

	%Free Protein S	
IL System	**Slope**	**r**
ACL Futura	0.92	0.981
ACL 9000	0.93	0.972

Within run precision assessed over multiple runs using three levels of control plasma gave the following results:

	%Free Protein S		
ACL Futura	**Normal Level**	**Abnormal Level 1**	**Abnormal Level 2**
Mean	97.70	57.03	22.41
% CV	1.94	2.70	2.91

	%Free Protein S		
ACL 9000	**Normal Level**	**Abnormal Level 1**	**Abnormal Level 2**
Mean	97.10	56.59	21.81
% CV	1.85	2.92	3.21

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 1 3 2001

Ms. Carol Marble
Regulatory Affairs Manager
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, Massachusetts 02421

Re: K010379
Trade Name: IL Test™ Free Protein S
Regulation Number: 21 CFR § 864.7290
Regulatory Class: II
Product Code: GGP
Dated: February 7, 2001
Received: February 8, 2001

Dear Ms. Marble:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K010379

Device Name: IL Test™ Free Protein S

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Division S
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510(k) Num

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓

Prescription Use _____ **OR** Over-The-Counter Use _____
(Per 21 CFR 801.019)